JENNIFER L. ISHIMOTO, SBN 211845
ishimoto@banishlaw.com
DAVID BANIE, SBN 217924
banie@banishlaw.com
JOHN A. LEE, SBN 229911
jlee@banishlaw.com
BANIE & ISHIMOTO LLP
1999 South Bascom Ave., Suite 700
Campbell, CA 95008
Telelphone: (650) 549-5660
Facsimile: (415) 665-2520

Attorneys for Defendants
Fuisz Pharma LLC, Richard C. Fuisz,
and Joseph M. Fuisz

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

THERANOS, INC. and ELIZABETH HOLMES,

Plaintiffs,

v.

FUISZ PHARMA LLC, RICHARD C. FUISZ, and JOSEPH M. FUISZ,

Defendants.

Case No. CV 11-05236 PSG

FUISZ PHARMA LLC'S, JOSEPH FUISZ'S, AND RICHARD FUISZ'S CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

The parties' claim construction provides two distinct paths for this case—one that is clear and defined (Fuisz Pharma) and another that is ethereal and nebulous (Plaintiffs).[1] The questions presented for the Court boil down to:

(1) Whether to adopt Fuisz Pharma's proposed constructions for the disputed terms based on the intrinsic evidence of record which will establish boundaries to the meaning of the disputed claim terms?; or

(2) Whether to adopt Plaintiffs' request that no construction of the disputed terms is necessary?

The problem with Plaintiffs' proposal is that it is clear that the parties have a dispute as to scope of the claim terms. Fuisz Pharma's proposed constructions set boundaries on the disputed terms, providing for example the basis to resolve the parties' disputes concerning inventorship and invalidity. The Court, as fact finder, will be able to weigh, assess, and provide sound reasoning on these issues. On the other hand, if no constructions are provided to the disputed terms as Plaintiffs insist, the case will move towards a murky and dark path destined to create confusion, result in additional arguments, such as whether certain prior art are relevant to the case or should be excluded or create additional mini-Markman disputes requiring the Court's intervention. This will waste judicial resources both for this Court in dealing with the above dispute and provide a high degree of challenge for the Federal Circuit to rule on the many appealable issues that will arise from the absence of true claim construction.

Plaintiffs' proposal is not only bad law, but completely contrary to Plaintiffs previous positions, including objecting to bifurcation and/or early summary judgment, where Plaintiffs argued that claim construction was necessary. Only now do Plaintiffs argue that no construction is necessary for any of the disputed terms.

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[1] "Fuisz Pharma" shall refer to Defendants Fuisz Pharma, Richard C. Fuisz, and Joseph M. Fuisz. "Plaintiffs" as used herein shall refer to Theranos, Inc. and Elizabeth Holmes.

The parties dispute the meaning of the terms as evidenced by Plaintiffs' unsupported allegations that in some instances Fuisz Pharma's constructions are too broad and in other instances too narrow, but provide no examples to support their allegations. During this case Plaintiffs have, and will continue, to stretch technical arguments in order to try and support their position that the four provisionals that they attached to their Second Amended Complaint as Exhibits A-D, either demonstrate that Plainitffs invented the '612 Patent or that they render the '612 Patent obvious. One such example, is that Plaintiffs insist that their provisional concerning ways to minimize calibration errors is about threshold values, even though the word "threshold" is never mentioned and the patent has nothing to do with the technology of the '612 Patent. This argument, however, paves the way for Plaintiffs to argue that anything addressing calibration error sets the same "threshold value" as the '612 Patent – which is clearly false. Should this Court not construe any of the disputed terms, the Plaintiff would have the freedom to go-ahead and continue to distort, twist, and misread the patent and prior art to suit its purpose—and would further magnify the parties dispute rather than resolve it. Accordingly, the Court should adopt Fuisz Pharma's proposed constructions.

II. TECHNOLOGY OVERVIEW

U.S. Patent No. 7,824,612, entitled, "Bodily Fluid Analyzer, and System Including Same and Method for Programming Same" ("'612 Patent") is directed towards a method and system for monitoring a patient's health based on that patient's medical condition.

The '612 Patent teaches the upfront determination of a threshold value for an analyte associated with the patient's drug regimen or course of medical treatment ("doctor selected threshold value"), based on a patient's medical condition selected by a doctor or drug company. (*See e.g.*, '612 Patent, Col. 4:20-67), as the following exemplars highlight:

- Teaching that personalized medical monitoring by accounting for a patient's medical condition. The '612 Patent for example teaches setting a wider creatinine tolerance for an 80-year-old patent than in a 20-year-old patient. ('612 Patent, Col. 4:16-24).

- For patients taking Furosemide, a drug that can elevate creatinine levels or lower potassium levels, the '612 Patent teaches setting a threshold value to monitor K levels outside 3.5 – 5.0 Meq/L or creatinine levels outside of 0.6-1.2 Mg/dL. ('612 Patent, Col. 4:28-49). The '612 Patent also emphasizes the importance of accounting for a patient's medical condition when selecting the doctor selected threshold value. For example setting the threshold value to 1.2 – 2.0 Mg/DL instead of 0.6 -2.0 Mg/DL in the instance where the patient's baseline creatinine threshold was 1.6 Mg/dL.

The doctor selected threshold value is stored in a data storage unit. The data storage unit for example, may be a drug container; a container with a patient's bodily fluids such as a vial of blood; or a container provided by the patient caregiver to a patient. (*See e.g.*, '612 Patent, Col. 3:31-35.). Other examples of data storage units for storing the doctor selected threshold value provided by the '612 Patent includes bar codes RFID tags, and magnetic stripes. (*See e.g.*, '612 Patent, Col. 3:31-43.).

With the '612 Patent, the person performing the test (*e.g.*, patient, nurse, laboratory technician, other medical personnel) does not have to program the doctor selected threshold value into the bodily fluid analyzer. Instead, the doctor selected threshold value is programmed into the bodily fluid analyzer by having the bodily fluid analyzer's data reader seek and obtain that doctor selected threshold value from the data storage unit. For example, the doctor sets a threshold value that is inputted into a bar code (data storage unit) attached to the patient's prescription. The patient uses the bodily fluid analyzer to have its reader scan the bar code to retrieve the doctor selected threshold value from the bar code. In this manner, operator error is eliminated with respect to incorrect setting of threshold values, yet the doctor can control the threshold level that is monitored for a particular patient. This method is especially important as at home bodily fluid analyzers for the patient to operate himself becomes more prevalent.

Once the doctor selected threshold value for the patient is programmed into the bodily fluid analyzer, when tests are run on bodily fluid samples the analyte level is determined by the

bodiy fluid analyzer. An alert is displayed if the analyte level exceeds the doctor selected threshold value for the patient.

III. PRINCIPLES OF CLAIM CONSTRUCTION

As the Court is very familiar with the principles of claim construction, Fuisz Pharma will not belabor the point here. Simply put, claim construction begins and ends in all cases with the actual words of the claim. *Renishaw PLC v. MarpossSocieta' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998). In *Phillips* the Federal Circuit made clear that any claim construction approach that sacrifices the intrinsic record in favor of the extrinsic record should be rejected. *Superspeed L.L.C. v. IBM Corp.,* U.S. Dist. LEXIS 10124 (E.D. Texas 2009) citing *Phillips v. AWH Corporation*, 415 F.3d 1303 (Fed. Cir. 2005).

Fuisz Pharma proposes constructions for the disputed '612 Patent claim terms in accordance with long-established principles of claim construction—giving a claim term its ordinary meaning that one of skill in the art, at the time of the invention and in light of the patent's specification and prosecution history. *See, e.g., Phillips*, 415 F.3d at 1316–17.

Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims. *U.S. Surgical Corp. v. Ethicon, Inc.,* 103 F.3d 1554, 1568 (1997). Seemingly ordinary terms must be construed when there is more than one definition for the term or when failure to construe the term does not solve the parties' dispute. *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co*., 521 F.3d 1351, 1361 (Fed. Cir. 2008).

IV. DISPUTED CLAIM CONSTRUCTIONS

The Court's construction of the disputed terms is necessary to resolve the parties dispute. Purporting to adopt a plain meaning approach – as Plaintiffs have – to terms on which the parties do not agree will not resolve the parties' dispute. It will only add fuel to the fire. Fuisz Pharma's proposed constructions are based on the ordinary meaning of what one of skill in the art would understand the terms to mean in light of the specification and prosecution history of the patent. Plaintiffs simply take the position that individual words themselves are common and well

understood and thus the entire disputed phrase is well understood and needs no construction. Yet at the very same time, Plaintiffs also conclusorily assert that some of Fuisz Pharma's proposed constructions are too narrow, too broad, vague, and ambiguous. Despite Plaintiffs' assurances, the parties dispute as to the meaning of these terms needs to be resolved by the Court. *O2 Micro*, 521 F.3d at 1359 (error to not construe the meaning of a disputed term when the parties have a dispute as to the meaning of the term).

A. "Setting the bodily fluid analyzer with at least one threshold value for the at least one analyte to be sensed by the bodily fluid analyzer with the information read by the data reader from the data storage unit"

Plaintiffs' Proposed Construction	Fuisz Pharma's Proposed Construction
Plain Meaning	Programming instructions into the device that measures bodily fluids with a lower limit and/or upper limit for at least one chemical substance being measured by a device that analyzes bodily fluids using the data the device reader obtained from the object that contains data and the object is not part of the device that analyzes bodily fluids

This disputed term requires:

- a doctor selected threshold value as required by the 1st element of claim 1;
- the doctor selected threshold value stored at a data store unit (which is separate from the bodily fluid analyzer as required by the 2nd element of claim 1); and
- the body fluid analyzer reads information from the data storage unit and obtains from that the doctor selected threshold value, which is used to program the bodily fluid analyzer.

The original application did not include the requirements of a bodily fluid analyzer, setting the bodily fluid analyzer, or a doctor selected threshold value. (*See* Ishimoto Decl., Ex. A, 4.24.07 Application). In response to an office action in February 2009, the patentee amended its claims to require a doctor selected threshold value, and that the data information storage unit containing the doctor selected threshold value be separate from the bodily fluid analyzer (*See* Ishimoto Decl., Ex. B, 2.20.09 Response to Office Action at 2,8,10.) The patentee explained that:

"applicants have amended the claims to more clearly define their invention. . . .

> Claims 1 and 7 have been amended to clarify that the data storage unit is provided separately from the bodily fluid analyzer . . . and to recite the stored information is set by the prescribing physician or drug company and includes at least one threshold value of at least one analyte to be sensed by the bodily fluid analyzer, the at least one threshold value of the analyte being associated with a particular drug being or course of treatment for the patient."

(*Id.* at 8-10.)

In a later amendment (February 2010), the patentee amended the claim clarifying that the data stored on the data storage unit is selected by the doctor and that the bodily fluid analyzer is set with the doctor selected threshold value after the bodily fluid analyzer reads the doctor selected threshold value from the data storage unit. (*See* Ishimoto Decl., Ex. C, 2.9.10 Supplemental Amendment at 8). As explained by the patentee:

- "claims 1 and 7 have been amended to clarify, as per the Examiner's suggestions at the interview of November 4, 2009, that the stored information is selected by a prescribing physician or a drug company and includes at least one threshold value of at least one analyte to be sensed by the bodily fluid analyzer, the at least one threshold value of the at least one analyte being associated with a particular drug being taken by the patient or course of treatment for this patient, and that this information is set in the bodily fluid analyzer" (Ex. C, 2.9.10 Supplemental Amendment at 8).

Likewise, the patent specification supports Fuisz Pharma's proposed construction, when it uses the following language to explain the setting of a threshold value on a bodily fluid analyzer:

- "setting at least one threshold value for at least one analyte to be sensed by the bodily fluid analyzer based on the information read by the data reader from the data storage unit, wherein the threshold value is associated with the particular" . ('612 Patent, Col. 2:21-29).
- "The present invention will enable the pill container via a reader to give full instructions to the analyzer as to what the fluid is and what parameter is to be measured." ('612 Patent, Col. 5:41-44) (programming the bodily fluid analyzer by reading the doctor selected threshold value from the data storage unit)
- "therefore, a drug container containing a thiazide diuretic would have a data storage unit on having data stored with preset parameters from which the processor can set at least one threshold value for K or Na, e.g., set alarms if the K level is

below 3.5 meq/L or the Na level is below 130 meq/L." ('612 Patent, Col. 4:62-67) (the data storage unit containing the threshold value is separate from the bodily fluid analyzer).

Fuisz Pharma's proposed construction of this term provides the ordinary meaning of what one of skill in the art would understand the disputed term to mean based on the specification and prosecution history of the '612 Patent. A construction is necessary given the parties dispute to the meaning of this disputed term. *O2 Micro*, 521 F.3d at 1359.

Plaintiffs' complain that Fuisz Pharma is "attempting to make an end-run around this Court's limits on the number of terms for construction." (Plaintiffs' Opening Br. At 5). This is simply false. The intrinsic record and the language used by the patentee in its application and subsequent communications with the Patent Examiner demonstrate that the phrase is looked at as a whole. The issue of exceeding the limit on the number of constructions has been raised for the very first time by Plainitffs and not once raised to Fuisz Pharma before Plaintiffs filed their brief. To support its position that this disputed term is really more than one disputed claim term, Plaintiffs take *Oracle Am., Inc. v. Google, Inc*., C 10-03561, 2011 WL 1565988, at *15 (N.D. Cal. Apr. 27, 2011) out of context. *Oracle* decided that the parties disputed claim term - "computer-usable medium", "computer readable storage medium", and "computer-readable medium"—involved six different patents and a prosecution history of more than a decade and exceeded the Court order of six disputed terms as the Court there had already construed five terms. In the present case, the above disputed phrase is at issue, there are no other variants as was the case in *Oracle* and only the '612 Patent is in dispute, instead of the six patents in *Oracle*.

Plaintiffs argues that Fuisz Pharma uses synonyms for "setting," "bodily fluid analyzer," "analyte," "to be sensed," "data reader," "read," and "data storage unit," and have mapped what they argue as "replacement language." Plaintiffs' reliance on *Am. Patent Dev. Corp.,* 604 F Supp 2d at 716 to support its position. But *Am. Patent Dev. Corp. v. Movielink, LLC*, 604 F. Supp. 20, 704, 716 (D. Del. 2009) supports Fuisz Pharma's position as the disputed term in *Am. Patent Dev.*

was "storing a result of said decoding step" and was construed by the *Am. Patent Dev.* court. Disputed terms should be construed.

Plainitiffs cite to *Parker-Hannifin Corp.*, 2008 WL 5732941, *10 (N.D. Ohio 2008) for the notion that "providing no construction for words which should be readily understood by a jury and where defendant's construction merely offered synonyms for the claim terms." (Plaintiff's Opening Br. at 7.) This is another case taken out of context and misapplied by Plaintiffs. The disputed term in *Parker-Hannifin Corp* was "Annular portion surrounding and defining a central opening" / "Said annular portion" / "The annular portion." The Court agreed that no further construction beyond defining "annular" to mean "configured or arranged as a ring" was required. The *Parker-Hannifin Corp* Court construed the parties disputed terms.

Plaintiffs' mistakenly assert that the Court's claim constructions will be jury instructions. Plaintiff made clear during the telephonic hearing on May 16, 2013, that the only actions it would proceed upon are equitable in nature – which have no right to a jury trial. *See Shum v. Intel Corp., et al.*, 499 F.3d 1272, 1277 (Fed. Cir. 2007) (stating that "the parties agreed that an action for correction of inventorship under § 256, standing alone, is an equitable claim to which no right to a jury attaches."); *see also In re Technology Licensing Corp.*, 423 F.2d 1286, 1290-1291 (Fed. Cir. 2005) (finding that a declaratory judgment claim for invalidity is only entitled to a jury trial only if there is an accompanying infringement claim that would give rise to a jury trial). Thus, the trial scheduled for November 2013 is a bench trial**.**

Contrary to Plaintiffs' assertion, Fuisz Pharma's proposed construction does not inject limitation into disputed claim term. For the "object is not part of the device that analyzed the bodily fluid", Fuisz Pharma is making clear that the limitation language in the earlier parts of the claim element apply to the "data storage unit". Plaintiff cannot and does not point out how Fuisz Pharma's construction is overly narrow. This again shows that the Parties have a genuine dispute requiring the Court's construction.

With respect to "analyte" Plaintiff seems to be taking the position that potassium is not a chemical compound because it is made up of only potassium molecules. To that extent, Fuisz

Pharma is agreeable that analyte means a "chemical substance"—and has revised its constructions with this change.

Plaintiffs also complain that Fuisz Pharma references "object" twice in this construction and that it is vague and ambiguous —Fuisz Pharma disagrees. Object is part of the construction pertaining to a data storage unit. Plaintiffs provide no reasoned analysis as to why this would narrow or broaden the ordinary meaning of this term.

Plaintiffs' position that no construction is necessary lacks merit since Plaintiffs repeatedly dispute what Fuisz Pharma believes to be the ordinary meaning of the disputed terms. Thus, there is no "plain meaning" that is agreed upon. Were the Court to provide no construction to the disputed claim terms – it would be a recipe for disaster, for example:

- Plaintiffs' will have the green light to creatively twist, stretch, and strain the meaning of the disputed terms to suit its purpose on inventorship and invalidity during summary judgment motions and at trial.
- Second, during the bench trial, with no constructions, there likely will be multiple mini-*Markmans* to address the parties' respective motions (for example, whether certain prior art is admissible for the invalidity portion of the trial).
- Third, were the case to go up on appeal, the Federal Circuit, would not have the reasoned basis for many of the Court's post-Markman decisions such as summary judgment rulings, JMOL rulings, or the Court's bench trial rulings concerning inventorship and invalidity.

Accordingly, the Court should adopt Fuisz Pharma's proposed construction.

B. "selecting by a prescribing physician or a drug company at least one threshold value of at least one analyte to be sensed by the bodily fluid analyzer"

Plaintiffs' Proposed Construction	Fuisz Pharma's Proposed Construction
Plain Meaning	Based on a patient's medical condition, a medical doctor or drug company determines, the lower limit and/or upper limit, for at least one chemical substance being measured by a device that analyzes bodily

	fluids

The '612 Patent is directed to personalized medical care and requires a doctor selected threshold value. Doctors and drug companies provide treatment and care to patients. Selecting a threshold value is an active decision based on a patient's medical condition. The intrinsic evidence supports Fuisz Pharma's construction that the threshold value is selected by a doctor based on a patient's medical condition, as highlighted below:

- "Alternatively, the data stored on the data storage units may store parameters that are set by the prescribing physician specifically for that particular patient or drug company for a class of patients (e.g., elderly)." ('612 Patent, Col. 4:11-15).
  - The data storage unit can have preset information selected by the doctor based on a patient's medical condition, in this example the medical condition takes into account whether the patient is elderly.
  - The drug company can put into the storage unit, preset parameters for the users of its drug based on their medical conditions
- "Alternatively, if, e.g., if the data storage unit stores preset parameters, the device may contain an input unit (physically connected or remotely connected) so that the physician can narrow or widen the parameters to meet the special physiology of a particular patient." ('612 Patent, Col. 4-15-24, *see also* '612 Patent, Col. 4:25-65).
  - If the preset parameters are appropriate for the patient's medical condition, the doctor adopts the preset parameters in the data storage unit – there would be no modification of the parameters in the data storage unit by the doctor. This is a selection by the doctor based on a patient's medical condition.
  - If the preset parameters do not work for a patient because of a patient's special physiology (medical condition), the doctor can adjust the parameters on the data storage unit. This is a selection of parameters by the doctor based on a patient's medical condition.

- "[T]he stored information is set by a prescribing physician or a drug company that includes at least one threshold value of at least one analyte to be sensed by the bodily fluid analyzer, the at least one threshold value of the at least one analyte being associated with a particular drug being taken or to be taken or course of treatment for the patient" (2.20.09 Response to Office Action at 8, *see also id* at 2,10).
    - The doctor is writing the prescription for the test for his/her patient and the stored information set by the prescribing doctor is information based on that patient's medical condition.

Without the language proposed by Fuisz Pharma, which Plaintiff says is objectionable, a doctor writing the prescription would not need to make a threshold value decision based on the patient's medical condition– allowing random choices or computer generated choices under Plaintiffs' view.[2]

Plaintiff also argue that the "based on medical condition" is inconsistent with claims 8 and 18, because "'class of patients' is not necessarily defined based on the patient's medical condition, but instead can be based on a factor such as age.'" Plaintiffs misread the '612 Patent as their cited passages concern a patient's medical condition that accounts for a patient's age. (Plaintiff's Opening Br. at 10). Finally, Fuisz Pharma's proposed construction does not create tension with the "class of patients" requirement for claims 8 and 18 because a class of patients can certainly share common medical conditions (e.g., genetic mutation, specific illness) that make it feasible for doctors to set a threshold value for that group of patients.

Fuisz Pharma's proposed construction is the plain and ordinary meaning that one of ordinary skill in the art would understand the term to mean. Plaintiffs disagree with the meaning and insist that no construction is necessary. Plaintiffs' position would not resolve the parties'

[2] Such view of medical care is alarming and not in the main stream. But Plaintiffs view is consistent with its view of algorthimic based care.

dispute – instead it would heighten the parties' dispute as the case progresses. Plaintiffs' behavior in this case thus far provide a good indicator of what lies ahead were their position of no construction adopted:

- During discovery, Plaintiffs have taken the position that certain of Theranos' provisionals contained the selection of a threshold value of an analyte when they really discuss algorithms that use multiple analytes to calculate various parameters[3];
- Further, Plaintiffs have insisted that Theranos' calibration error provisional concerns threshold values. A plain reading of that provisional shows that not once does Theranos' calibration provisional mention a threshold.

Fuisz Pharma's constructions should be adopted because there is a dispute as to the meaning of this term and its construction provides tangible boundaries to the meaning based on what of one of ordinary skill in the art understands the disputed term to mean.

C. "the at least one threshold value of the at least one analyte being associated with a particular drug or to be taken by the patient or course of treatment for the patient

Plaintiffs' Proposed Construction	Fuisz Pharma's Proposed Construction
Plain Meaning	the lower limit and/or upper limit of a chemical substance that is analyzed and is related to a drug taken by a patient, or a drug taken by a patient, or medical treatments set for the patient

Fuisz Pharma's proposed construction is the ordinary meaning of what one of ordinary skill in the art understands this disputed term to mean. The parties disagree to the meaning of this disputed term and thus a construction from the Court is necessary to resolve the parties' dispute. *O2 Micro Int'l*, 521 F.3d at 1359. (opining that "[i]n many cases, the meaning of a claim term as understood by persons of skill in the art is not readily apparent" and finding that the trial court

[3] For example, Theranos' Invalidity Contentions.

erred in declining to construe a disputed claim term).

Intrinsic evidence supports Fuisz Pharma's construction as the following highlights:

- "e.g., the data storage unit may be used to program the device to set alarms when the K level is outside the range of 3.5-5.0 Meq/L." ('612 Patent, Col. 4:60-65).
  - setting both an upper limit and a lower limit
- "For example, the data storage unit associated with a drug container containing Lipitor TM can set ALT>150iu/L as an upper limit (normal is 48)." ('612 Patent, Col. 4:50-52).
  - setting an upper limit
- "Therefore, a drug containing a thiazide diuretic would have a data storage unit on having data stored with preset parameters from which the processor can set at least one threshold value for K or Na, e.g., set alarms if the K level is below 3.5 Meq/L or the Na level is below 130 meq/L." ('612 Patent, Col. 4:62-67, see also 2.20.09 Response to Office Action at 2,8,10; 2.9.10 Response to Office Action at 8).
  - setting a lower limit

For, "associated", "analyte", and "course of treatment" in this disputed term, Plaintiffs argue that Fuisz Pharma's proposed construction is replacement language and thus no construction is necessary for the entire disputed term. The whole point of claim construction is to define the meaning of disputed terms, and apparently, the parties are in agreement with respect to what these words mean, but dispute the meaning of the overall claim term.

Given the parties dispute to the meaning this term, the Court should adopt Fuisz Pharma's proposed construction.

D. "data unit storage separately from the bodily fluid analyzer"

Plaintiffs' Proposed Construction	Fuisz Pharma's Proposed Construction
Plain Meaning	An object that contains data and is not part of the device that analyzes bodily fluids

Fuisz Pharma's proposed construction is the ordinary meaning of what one of skill in the

art would understand the term to mean. A "data storage unit" is an "object that contains data" as supported by the intrinsic record:

- "The *data storage unit may be provided with a drug container* or otherwise supplied by a care giver to the patient. For example, *the data storage unit can be a bar code* and the data reader can be a bar code reader; the data storage unit can be a magnet stripe and the data reader a magnetic strip reader." ('612 Patent, Col. 3:32-38).
- "A drug container includes a data storage unit." ('612 Patent, Col. 4:4-5).
- "In the future, the drug itself may contain the information read through its individual package or through a microchip in the dosage form itself." ('612 Patent, Col. 6:8-10).

This disputed claim term also requires the data storage unit to be "separately from the bodily fluid analyzer" which Fuisz Pharma proposes to mean "not part of the device that analyzes bodily fluids." Plainitffs' object and argue that "not part of" is absent from the intrinsic record. Not so. The intrinsic record cites above demonstrate that the data storage unit is not part of the bodily fluid analyzer with the data storage unit being a bar code, a RFID tag, drug packaging, or in the future incorporated into the drug itself. ('612 Patent, Col. 5:1-19, 6:1-10).

If the terms are easily understood as Plainitiffs assert—why do Plainitffs disagree that "separately" means "not part of the device that analyzes bodily fluids"? Do they want to argue that the bodily fluid analyzer can contain the data storage unit? Not adopting Fuisz Pharma's proposed construction would not preclude Plaintiffs from making such an argument.

The Court should adopt Fuisz Pharma's proposed construction and decline Plaintiffs' request for no construction.

E. "reading the stored information stored on the data storage unit"

Plaintiffs' Proposed Construction	Fuisz Pharma's Proposed Construction
Plain Meaning	The bodily fluid analyzer makes a request to access information stored on the data storage unit and selected by the medical doctor or

	drug company, that includes the threshold value, looking up that information, and obtaining a copy of that information that includes the threshold value

Fuisz Pharma's proposed construction of "reading the stored information stored on the data storage unit" provides clarity to a technical term "reading" in the context of the technology of the '612 Patent, cannot simply be written off by Plaintiffs' mantra that the terms are well understood and no construction is necessary.

There are many aspects to the '612 Patent. The data storage unit (separate from the bodily fluid analyzer) contains data including the threshold value. The bodily fluid analyzer needs to access that information in order for it to be programmed with the doctor selected threshold value—so that when it runs its analytical tests on bodily fluid samples, it can determine whether the doctor threshold value is exceeded or not. The claim language specifically requires "reading", a process that requires the reader in the bodily fluid device to make a request for the information, get access by looking at the information, and making a copy of that information for use by the bodily fluid analyzer. The intrinsic record provides several examples of reading:

- "Thus, the patient can merely *scan* the bar code, *move the radio frequency identification tag near the reader or swipe the magnetic strip so that the data* associated with the particular drug being or to be taken by the patient or course of treatment for the patient *is read in a simple and fool proof m*anner." ('612 Patent, Col. 3:38-42) (emphasis added).
    - In each instance, the data reader is actively gaining access to the information stored elsewhere, looking up the info that is needed for the analyzer, and obtaining a copy of that information for the data reader.
- "The data unit reader 4 reads information from a data storage unit 7, the data storage unit 7 containing stored information concerning a particular drug being or to be taken by the patient or course of treatment for the patient." ('612 Patent, Col. 4:5-9, Fig. 1-6).

These examples support Fuisz Pharma's proposed construction for this technical term.

Plaintiffs' allegations that Fuisz Pharma's proposed construction "improperly and unreasonably narrows" the claim lacks merit as evidenced by Plaintiffs' failure to point to a single concrete example of a "reading" that is read out by Fuisz Pharma's proposed construction.

F. "a/the display"

Plaintiffs' Proposed Construction	Fuisz Pharma's Proposed Construction
Plain Meaning	An output surface for visual presentation of information

Fuisz Pharma's proposed construction for this disputed term should be adopted by the Court as it is in harmony will the intrinsic record that the display is a visual presentation of information:

- "displaying an alert if the sensed analyte level is beyond the threshold value" ('612 Patent, Col. 2:28-29)
- "a display for displaying processed information concerning the sensed analyte"
- "the processeor processes this information to display it on the display so the patient does not put the wrong cartridge (i.e., a cartridge for the wrong drug) in the analyzer".

Plaintiffs fails to provide any concrete examples as to how Fuisz Pharma's proposed construction broadens or narrows the meaning of "a/the display". Moreover, Plaintiffs were apparent agreement with Fuisz Pharma's proposed construction for this term, stating:

- "Upon further reflection, we have decided to adopt plain meaning for the term "a/the display." We believe that plain meaning is consistent with our prior proposed construction, and to the extent we understand your proposed construction, consistent with, or at least similar to, it as well." (Ishimoto Decl., Ex. D, 6.27.13 Michael Jay e-mail to Jennifer Ishimoto).

The Court should provide a construction for this disputed term. Providing no construction as Plaintiffs' request will not resolve the parties dispute. It will only result in continual disputes as to what is the plain and ordinary meaning and require the Court to intervene each and every

time there is a dispute for the case moving forward.

G. "a threshold value"

Plaintiffs' Proposed Construction	Fuisz Pharma's Proposed Construction
Plain Meaning	The lower limit and/or upper limit

As explained in detail in Section II.C above, the intrinsic record shows the threshold value being an upper limit, a lower limit, and/or having both an upper and lower limit. When this analyte level exceeds this limit, an alert is displayed. If the analyte level does not exceed the limit, an alert is not displayed.

Plaintiffs' reliance on the specification about "program[ming] the device to set alarms when the K level is outside the range of 3.5-5.0 Meq/L is an example of a an upper and lower limit – if the value falls inside of 3.5-5.0 Meq/L, the limit is not exceeded an no alarm is set off, while the value of K falls outside of 3.5-5.0 Meq/L the limit is exceeded and an alarm is set off.

Plainitffs' conclusory assertion that Fuisz Pharma's proposed construction impermissibly limits the meaning of this term is without merit. As evidenced by the fact that it cannot provide even one example of a threshold value that would be excluded by Fuisz Pharma's construction for this term.

V. CONCLUSION

For the reasons set forth above, the Court should adopt Fuisz Pharma's proposed constructions.

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BANIE & ISHIMOTO LLP

By /s/ Jennifer L. Ishimoto

JENNIFER L. ISHIMOTO, SBN 211845
ishimoto@banishlaw.com
DAVID BANIE, SBN 217924

banie@banishlaw.com
JOHN A. LEE, SBN 229911
jlee@banishlaw.com
BANIE & ISHIMOTO LLP
1999 South Bascom Ave., Suite 700
Campbell, CA 95008
Telelphone: (650) 549-5660
Facsimile: (415) 665-2520